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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,196	03/04/2002	Joseph P. Day	SP01-310 WJT003-0010	4725
22928	7590	06/23/2004	EXAMINER	
CORNING INCORPORATED			MUTSCHLER, BRIAN L	
SP-TI-3-1				
CORNING, NY 14831			ART UNIT	PAPER NUMBER

1753

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/090,196	Applicant(s) DAY ET AL.	
	Examiner Brian L. Mutschler	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference character(s) mentioned in the description: **102a** and **102b** (see e.g., p. 10, line 17). Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims are indefinite because there is no method step that corresponds to the "enabled" process recited in each of claims 26-31. For example, claim 26 recites that "said inorganic media enables a combination of mass

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spectroscopy and electrophoresis" but does not recite a positive step of performing mass spectroscopy and electrophoresis. In addition, the claim does not recite how the media is "enabled" to perform such a process. The same applies to claims 27-31.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Elmer ("Porous and Reconstructed Glasses", Engineered Materials Handbook, Vol. 4, Ceramics and Glasses, p. 427-432 (1992)).

Regarding claims 1-4, 7, and 8, Elmer discloses material capable of being used in size-exclusion processes for separating nucleic acids and proteins, wherein the material comprises alkali borosilicate glass and controlled pore glass (see p. 428-429). The material has pore sizes that can range from 75Å to 3000Å (p. 428-429).

Since Elmer teaches all of the structural limitations recited in the instant claims, the reference is deemed to be anticipatory.

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6. Claims 1, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Cortes et al. ("Porous Ceramic Bed Supports for Fused Silica Packed Capillary Columns Used in Liquid Chromatography", Journal of High Resolution Chromatography & Chromatography Communications, Vol. 10, p. 446-448 (August 1987)).

Regarding claims 1, 5, and 6, Cortes et al. disclose an inorganic material for liquid separations comprising a monolithic sol-gel having a pore size of 3000Å to 5000Å (p. 446).

Since Cortes et al. teach all of the structural limitations recited in the instant claims, the reference is deemed to be anticipatory.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 9, 10, 15-19, and 24-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington et al. (U.S. Pat. No. 5,637,202).

Regarding claims 9 and 17, Harrington et al. disclose an apparatus and method of using that apparatus, wherein a porous separating media **12** is placed in an electrophoresis buffer (fig. 1; col. 4, lines 53-67). A power supply **18** is attached to electrodes **14** and **16**, which are immersed in the buffer at opposite ends of the separation media **12** (fig. 1; col. 4, lines 53-67). The porous separation media **12** is a

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polymer sponge, which is substituted for conventional electrophoresis materials, which include powdered and porous solids, fibrous materials, and gels (col. 1, lines 16-28; col. 4, lines 53-67). The powdered and porous materials include silica and glass (col. 1, lines 16-28).

Regarding claims 10 and 19, the conventional separation media includes porous glass (col. 1, lines 16-28).

Regarding claims 15-17, 24, and 25, biological samples including nucleic acids and proteins are separated using the apparatus and method (col. 5, lines 26-41).

Regarding claim 18, Harrington et al. further disclose the steps of staining and visually identifying proteins, as well as photographing the proteins during electrophoresis (col. 6, lines 39-47; col. 7, lines 49-56).

Regarding claims 26-31, since the separation media **12** is a substitute for conventional separation media, the separation media **12** is therefore enabled to perform each of the recited processes, which are conventional processes ordinarily performed by the conventional separation media.

The apparatus and method of Harrington et al. differs from the instant invention because Harrington et al. does not disclose that the separation media is an inorganic separation media.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the polymer sponge separation media used in the apparatus and method of Harrington et al. to use an inorganic separation media such as porous glass or silica because Harrington et al. teaches that the polymer sponge

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separation media is a direct substitute for conventional separation media such as porous silica and glass.

9. Claims 11, 12, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington et al. (U.S. Pat. No. 5,637,202), as applied above to claims 9, 10, 15-19, and 24-31, and further in view of Elmer ("Porous and Reconstructed Glasses", Engineered Materials Handbook, Vol. 4, Ceramics and Glasses, p. 427-432 (1992)).

Harrington et al. describe an apparatus and method having the limitations recited in claims 9, 10, 15-19, and 24-31 of the instant invention, as explained above in section 8.

Regarding claims 12 and 21, Harrington et al. disclose that the separation media (i.e., the polymer sponge **12**) should have pore sizes of sufficient size to allow electrophoretic migration of the proteins or nucleic acids, and provide preferred ranges of 0.1 μ m to 25 μ m (1000Å to 250,000Å) for proteins and 1 μ m to 100 μ m (10,000Å to 1,000,000Å) for nucleic acids (col. 5, lines 26-41).

The apparatus and method of Harrington et al. differs from the instant invention because Harrington et al. do not disclose the following:

- a. The porous glass is alkali borosilicate glass, as recited in claims 11 and 20.
- b. The porous glass has pores with an average pore diameter greater than 100Å, as recited in claims 12 and 21.

Regarding claims 11, 12, 20, and 21, Elmer discloses material capable of being used in size-exclusion processes for separating nucleic acids and proteins, wherein the material comprises alkali borosilicate glass and controlled pore glass (see p. 428-429). The material has pore sizes that can range from 75Å to 3000Å (p. 428-429).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the separation media of Harrington et al. to use an alkali borosilicate glass separation media having a pore size greater than 100Å as taught by Elmer because Elmer teaches that such separation media is suitable for the separation of nucleic acids and proteins.

10. Claims 13, 14, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington et al. (U.S. Pat. No. 5,637,202), as applied above to claims 9, 10, 15-19, and 24-31, and further in view of Malik et al. (US 2003/0213732) and Cortes et al. ("Porous Ceramic Bed Supports for Fused Silica Packed Capillary Columns Used in Liquid Chromatography", Journal of High Resolution Chromatography & Chromatography Communications, Vol. 10, p. 446-448 (August 1987)). US 2003/0213732 claims priority from U.S. Provisional Application No. 60/181,371, filed February 9, 2000, which provides full support for the subject matter relied upon in the following rejection.

Harrington et al. describe an apparatus and method having the limitations recited in claims 9, 10, 15-19, and 24-31 of the instant invention, as explained above in section 8.

Regarding claims 13 and 22, Harrington et al. disclose that conventional separation media includes porous silica (col. 1, lines 16-28).

Regarding claims 14 and 23, Harrington et al. disclose that the separation media (i.e., the polymer sponge **12**) should have pore sizes of sufficient size to allow electrophoretic migration of the proteins or nucleic acids, and provide preferred ranges of 0.1 μ m to 25 μ m (1000Å to 250,000Å) for proteins and 1 μ m to 100 μ m (10,000Å to 1,000,000Å) for nucleic acids (col. 5, lines 26-41).

The apparatus and method of Harrington et al. differs from the instant invention because Harrington et al. do not disclose the following:

- a. The inorganic separating media is a sol gel monolith, as recited in claims 13 and 22.
- b. The sol gel monolith has an average pore diameter greater than 100Å, as recited in claims 14 and 23.

Regarding claims 13, 14, 22, and 23, Malik et al. disclose a separation media for use in capillary electrochromatography, which is a type of electrophoretic separation (par. [0004]). The separation media comprises a monolithic sol gel made of a silicate material, such as the material taught by Cortes et al. (par. [0015]).

Cortes et al. disclose an inorganic material for liquid separations comprising a monolithic sol gel having a pore size of 3000Å to 5000Å (p. 446).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the separation media of Harrington et al. to use a

monolithic sol gel as taught by Malik et al. and Cortes et al. because Malik et al. teach that such materials are suitable for the separation of materials.

11. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington et al. (U.S. Pat. No. 5,637,202), as applied above to claims 9, 10, 15-19, and 24-31, and further in view of Kaltenbach et al. (U.S. Pat. No. 5,641,400), with further support provided by Guzman (U.S. Pat. No. 5,202,010).

Harrington et al. describe an apparatus and method having the limitations recited in claims 9, 10, 15-19, and 24-31 of the instant invention, as explained above in section 8.

Regarding claim 32, Harrington et al. further teach the use of the separation media in "any of the other well-known shapes typically employed in gel electrophoresis systems" (col. 4, lines 43-52). Harrington et al. also teach that the separation media may include porous materials such as cellulose and glass, as well as gels (col. 1, lines 16-28).

The method of Harrington et al. differs from the instant invention because Harrington et al. do not disclose the use of the separation media in a microscale total analysis system.

Kaltenbach et al. disclose a microscale total analysis system and teach the use of separation media in the miniaturized columns, wherein the separation media is selected from porous medium such as cellulose, nylon, polyacrylamide, or agarose (col. 17, lines 3-13).

Guzman teaches that columns may be filled with separation media such as porous glass and acrylamide or agarose (col. 15, lines 8-20; col. 16, lines 1-4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Harrington et al. to use the separation media in a microscale total analysis system as taught by Kaltenbach et al. because such a μ -TAS device operates more efficiently by utilizing smaller sample volumes. (As Guzman teaches, inorganic materials may be used in the same manner as organic materials as separation media in small-scale columns and devices.)

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

WO 99/38006 discloses a method for forming inorganic, monolithic sol gels in a capillary that have pore sizes larger than 100Å (see page 10, line 15).

U.S. Pat. No. 6,136,187 (Zare et al.) discloses a separation column containing a sol gel glass.

US 2002/0195344 (Neyer et al.) discloses an electrokinetic device using separation media as taught by Yazawa ("Present Status and Future Potential of Preparation of Porous Glass and its Application", Key Engineering Materials, Vol. 115, p. 125-146 (1996)).

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U.S. Pat. No. 6,638,408 (Speicher et al.) teaches a electrophoretic separation device using porous glass membranes that have a pore size of 5000Å (see col. 5, line 55 to col. 6, line 3).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian L. Mutschler whose telephone number is (571) 272-1341. The examiner can normally be reached on Monday-Friday from 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BLM
June 15, 2004


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